

IN THE CLAIMS:

1. **(Currently amended)** A botanical drug or dietary supplement, for the treatment of or for use in patients with Hepatitis C infection, ~~comprising botanical raw materials, botanical drug substances or botanical ingredients~~ consisting essentially of extracts from ~~each of~~ the following plant species sources:

- (a) ~~The~~ the fruit of Silybum marianum;
- (b) ~~The~~ the root of Astragalus membranaceus var mongholicus or Hedysarum polybotrys;
- (c) ~~The~~ the root of Salvia miltiorrhiza, Salvia bowleyana or Salvia przewalskii; and
- (d) ~~The~~ the fruit of Schisandra chinensis or Schisandra sphenanthera.

2. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 1 wherein each species is present in an amount, relative to the total weight of all ~~of the botanical raw materials, botanical drug substances or botanical ingredients~~ extracts, as follows:

- (a) Silybum ~~spp.~~ from 22-48%;
- (b) Astragalus ~~spp.~~ or Hedysarum ~~spp.~~ from 20-63%;
- (c) Salvia ~~spp.~~ from 13-48%; and
- (d) Schisandra ~~spp.~~ from 2-19%.

3. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 2 wherein each species extract is present in an amount by weight percent as follows:

- (a) Silybum ~~spp.~~ from 30-40%;
- (b) Astragalus or Hedysarum ~~spp.~~ from 20-30%;
- (c) Salvia ~~spp.~~ from 20-30%; and
- (d) Schisandra ~~spp.~~ from 7.5-15%.

4. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 3 wherein each species extract is present in an amount by weight percent as follows:

- (a) Silybum ~~spp.~~ about 35%;
- (b) Astragalus or Hedysarum ~~spp.~~ about 26%;
- (c) Salvia ~~spp.~~ about 26%; and
- (d) Schisandra ~~spp.~~ about 11%.

5. **(Cancelled)**

6. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[5]] 1 further ~~comprising~~ including excipients.

7. **(Cancelled)**

8. **(Cancelled)**

9. **(Cancelled)**

10. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein the ~~botanical drug substance~~ extract from ~~the~~ Silybum spp. is ~~standardised~~ standardized against a marker of silybin.

11. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein the ~~botanical drug substance~~ extract from ~~the~~ Silybum spp. comprises at least 30% by weight silybin and isosilybin when calculated using HPLC.

12. **(Currently amended)** A botanical drug or dietary supplement as claimed in ~~any of~~ claim [[9]] 10 wherein the ~~standardised~~ standardized extract of ~~the~~ Silybum spp. is a brownish yellow powder which ~~is or~~ has:

- (i) no less than 30% silybin by HPLC;
- (ii) no more than 0.5% soluble in pentane;
- (iii) a sulphated ash content of no more than 1% by weight;
- (iv) a heavy metal content of no more than 100ppm;
- (v) a residual organic solvent content of no more than 1% ethanol, no more than 0.01% ethyl acetate and no more than 0.01% hexane by weight;
- (vi) a bacterial content of no more than 1000 cfu/g; and
- (vii) a fungal content of no more than 100cfu/g.

13. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein the ~~botanical drug substance~~ extract from ~~the~~ Astragalus spp. is standardised against a marker of Astragaloside IV.

14. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 13 wherein the ~~botanical drug substance~~ extract from ~~the Astragalus spp.~~ comprises at least 0.4% by weight Astragaloside IV when calculated using HPLC.

15. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 13 wherein the ~~botanical drug substance~~ extract from ~~the Astragalus spp.~~ has a TLC chromatographic fingerprint substantially as illustrated in Fig 1 or a HPLC fingerprint substantially as illustrated in Fig 4.

16. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 13 wherein the ~~standardised~~ standardized extract of ~~Astragalus spp.~~ is a pale yellow powder which ~~is or~~ has:

- (i) no less than 0.4% Astragaloside IV by weight;
- (ii) a total ash content of no more than 5% by weight;
- (iii) an acid insoluble ash content of no more than 2% by weight; and
- (iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.

17. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim ~~[[9]]~~ 1 wherein the ~~botanical drug substance~~ extract from ~~the Salvia spp.~~ is standardised against a marker of Tanshinone II A.

18. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 17 wherein the ~~botanical drug substance~~ extract from ~~the Salvia spp.~~ comprises at least 1.5% by weight of Tanshinone IIA as calculated using HPLC.

19. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 17 wherein the ~~botanical drug substance~~ extract from ~~the Salvia spp.~~ has a TLC chromatographic fingerprint substantially as illustrated in Fig 2 or a HPLC fingerprint substantially as illustrated in Fig 6.

20. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 17 wherein the ~~standardised~~ standardized extract of ~~the Salvia spp.~~ is a dark red powder which ~~is or~~ has:

- (i) no less than 1.5% by weight Tanshinone IIA by HPLC;
- (ii) a total ash content of no more than 5% by weight;
- (iii) an acid insoluble ash content of no more than 2% by weight; and
- (iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.

21. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein ~~botanical drug substance~~ the extract from ~~the Schisandra spp.~~ is ~~standardised~~ standardized against a marker of Schizandrol A.

22. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 21 wherein the ~~botanical drug substance~~ extract from ~~the Schisandra spp.~~ comprises at least 2.0% by weight Schizandrol A using HPLC.

23. **(Currently amended)** A botanical drug ~~substance, or dietary supplement~~ as claimed in claim 21 wherein the ~~botanical drug substance~~ extract from ~~the Schisandra spp.~~ has a TLC chromatographic fingerprint substantially as illustrated in Fig 3 or a HPLC fingerprint substantially as illustrated in Fig 8.

24. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 22 wherein the ~~standardised~~ standardized extract of ~~Schisandra spp.~~ is a brownish red powder which ~~is or~~ has:

- (i) no less than 2.0 % by weight Schizandrol A;
- (ii) a total ash content of no more than 5% by weight;
- (iii) an acid insoluble ash content of no more than 2% by weight; and
- (iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.

25. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein ~~the standardised~~ each extract is a dried ethanolic extract.

26. **(Cancelled)**

27. **(Cancelled)**

28. **(Cancelled)**

29. **(Cancelled)**

30. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 which is provided in a unit dosage form.

31. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 ~~which is~~ wherein the extracts are a suspension powder mixture.

32. **(Currently amended)** A botanical drug or dietary supplement as claimed in ~~claims 31~~ claim 1 further ~~comprising~~ including as excipients:

(a) at least one ~~or more gellants~~ gellant or ~~thickeners~~ thickener comprising at least one xanthum gum having a particle size distribution such that 100% by weight of the particles pass a 60 mesh sieve, 95% by weight of the particles pass a 80 mesh sieve and 70% by weight of the particles pass a 200 mesh sieve,

(b) at least one ~~or more fillers~~ filler; and

(c) at least one ~~or more wetting agents~~ agent and or ~~surfactants~~ surfactant.

33. **(Currently amended)** A botanical drug or dietary supplement as claimed in ~~claims~~ claim 32 wherein the xanthan gum has a molecular weight of from 3.5×10^6 to 4.0×10^6 .

34. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 32 wherein the wetting agent is a polyethylene glycol or macrogol.

35. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 further ~~comprising~~ including one or more of a disintegrating agent, a lubricant, a sweetening agent, a flavouring agent and a viscosifying agent.

36. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 ~~which is~~ wherein the extracts are packaged in a sachet.

37. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 which is packaged with a dispensing container.

38. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 37 wherein the dispensing container has a sealable lid.

39. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] ~~1 comprising~~ wherein said extracts are botanical drug substances in [[a]] the following unit dose doses:

- (i) 0.200g to 0.250g of a botanical drug substance from [[a]] ~~*Silybum spp.*~~;
- (ii) 0.585g to 1.95g of a botanical drug substance from [[a]] ~~*Astragalus spp.*~~;
- (iii) 0.225g to 0.375g of a botanical drug substance from [[a]] ~~*Salvia spp.*~~; and
- (iv) 0.150g to 0.600g of a botanical drug substance from [[a]] ~~*Schisandra spp.*~~.

40. **(Currently amended)** A method of treating a patient to reduce or alleviate the symptoms of Hepatitis, particularly Hepatitis C, or to support healthy liver function comprising administering to a patient an efficacious dosage of [[a]] the botanical drug or dietary supplement as claimed in claim 1.

41. **(Currently amended)** The use of a botanical drug or dietary supplement to reduce or alleviate the symptoms of Hepatitis, particularly Hepatitis C, or to support healthy liver function, comprising administering to a patient an efficacious dosage of the botanical drug or dietary supplement as claimed in claim 1 in combination with another drug, said another drug being present in an amount efficacious to reduce or alleviate the symptoms of Hepatitis, ~~particularly~~ Hepatitis C, or to support healthy liver function.

42. **(Currently amended)** The use as claimed in claim 41 wherein the another drug is interferon.

43. **(Cancelled)**

44. **(Cancelled)**

45. **(Cancelled)**

46. **(Cancelled)**

47. (Cancelled)

48. (Cancelled)

49. (Cancelled)